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NTSB Order No. EA-4941

UNITED STATES OF AMERICA
NATIONAL TRANSPORTATION SAFETY BOARD
WASHINGTON, D.C.

Adopted by the NATIONAL TRANSPORTATION SAFETY BOARD
at its office in Washington, D.C.
on the 25th day of January, 2002

Petition of ROBERT STEVEN WADE, For a Review of the Denial by the Administrator of the Federal Aviation Administration of the Issuance of an Airman Medical Certificate.	)	Docket SM-4333

OPINION AND ORDER

Petitioner appeals the June 7, 2000 decision of Administrative Law Judge William R. Mullins,[1] denying petitioner's challenge of the Administrator's denial of petitioner's application for an unrestricted, first-class airman medical certificate, pursuant to sections 67.113(b), 67.213(b)

[1] The initial decision is attached.

and 67.313(b) of the Federal Aviation Regulations ("FARs").[2] We grant petitioner's appeal.

Petitioner is a DC-9 Captain for Northwest Airlines. On August 19, 1997, during a routine medical examination by Dr. Gerald W. Bock, an FAA-designated Aviation Medical Examiner (AME) for Northwest Airlines, petitioner was tentatively diagnosed with idiopathic hypertrophic subaortic stenosis (IHSS), and issuance of his medical certificate was deferred pending additional

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[2] Sections 67.113(b)(1), 67.213(b)(1) and 67.313(b)(1), 14 C.F.R. Part 67, constitute a set of identical provisions relating to first-, second-, and third-class medical certificates. We cite here, in relevant part, only the first-class provisions in the set:

> § **67.113 General medical condition.**
> The general medical standards for a first-class airman medical certificate are:
> * * *
> (b) No other organic, functional, or structural disease, defect, or limitation that the Federal Air Surgeon, based on the case history and appropriate, qualified medical judgment relating to the condition finds—
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> (1) Makes the person unable to safely perform the duties or exercise the privileges of the airman certificate applied for or held; or
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> (2) May reasonably be expected, for the maximum duration of the airman medical certificate applied for or held, to make the person unable to perform those duties or exercise those privileges.
> * * *

At the hearing, the manager of the FAA's Office of Medicine testified that the FAA offered petitioner a restricted, second-class certificate. The Board has no jurisdiction to review matters pertaining to a restricted medical certificate, however, and this opinion only pertains to petitioner's qualification to obtain unrestricted medical certification.

testing. Subsequently, over the course of the next several weeks, petitioner submitted to additional testing, including an echocardiogram, thallium stress tests, an ECG, and blood work, by Dr. Roger J. Cunningham, a cardiologist, and his associate, Dr. M. Brent Addington. Dr. Addington noted, in his August 20, 1997 echocardiography consultation report, that petitioner's left atrium was "[d]ialated" to 51 millimeters [("mm")] and that he had a left ventricular wall thickness of 19 mm, "consistent with left ventricular hypertrophy." Dr. Addington's report concluded that petitioner has asymmetric septal hypertrophy consistent with IHSS. Dr. Addington's report also noted that petitioner had a "[p]eak gradient across the aortic valve of 3.3 [meters per second] consistent with outflow tract obstruction." Dr. Addington's report also noted that the echocardiogram showed that petitioner had "systolic anterior motion of the mitral valve consistent with IHSS" and an increased "a" wave "across the mitral valve consistent with left ventricular non-compliance." Joint Appendix ("JE") at 181-182. Dr. Cunningham concluded that "the diagnosis of hypertrophic cardiomyopathy [("HCM")] with obstruction is very clear." Dr. Cunningham recommended no treatment because petitioner was asymptomatic, but anticipated monitoring petitioner's condition "at intervals." JE at 172-174.

HCM is a disease of the heart muscle, usually evidenced by an abnormal thickening of the ventricular septum. Transcript

("Tr.") I at 299.[3] Even though the ventricular heart wall thickens, the heart cavity remains small or normal sized. Tr. I at 233. HCM is a heterogeneous disease; not all patients with HCM have the same features. Tr. I at 229-230; 232. However, common features of HCM patients are outflow obstruction (a non-constant obstruction of the flow of blood from the left side of the heart to the aorta), diastolic dysfunction (improper filling of the left ventricle), and acute atrial fibrillation (causing the atria to no longer properly contract, and, in HCM patients, potentially resulting in reduced diastolic filling and cardiac output). Tr. I at 234-237; 240; 327. A minority of HCM patients, less than one-third, also have an enlarged left atrium. Tr. I at 238.

The reports of Drs. Addington and Cunningham, along with the underlying raw data, were forwarded to the FAA Aeromedical Certification Division, where they were reviewed by a panel of FAA cardiological consultants. The FAA cardiological consultants recommended that petitioner be denied airman medical certification, and, by letter of October 9, 1997, Dr. Stephen Carpenter, of the FAA Aeromedical Certification Division, denied petitioner's application for an unrestricted airman medical certificate. Dr. Carpenter's letter explained that petitioner's

[3] The hearing was bifurcated. Transcript I refers to the December 14, 1999 portion of the hearing. Transcript II refers to the January 10, 2000 portion of the hearing.

medical certificate application was denied pursuant to Federal Aviation Regulation ("FAR") sections 67.113(b), 67.213(b) and 67.313(b) because of "available information which reveals a history of asymmetric septal hypertrophy and [IHSS]." JE at 17.

After the FAA denial of his medical certificate application, petitioner sought legal counsel, who contacted Dr. Barry J. Maron, Director of Cardiovascular Research at the Minneapolis Heart Institute and an expert on HCM, for additional evaluation. Dr. Maron requested that petitioner undergo additional testing, which petitioner elected to have performed in Puerto Rico by Dr. Raul A. Jiminez. Dr. Jiminez's tests included ECGs, a color Doppler continuous wave electrocardiogram, several other electrocardiograms, and a 24-hour Holter monitor. In a December 17, 1997, report addressed to Dr. Cunningham, Dr. Jimenez stated that petitioner "underwent an echocardiographic examination that showed marked hypertrophy of the basal septum, and mild hypertrophy of the other segments." Dr. Jiminez's report also stated that petitioner's "IV septum showed a wall thickness of 2.0 [centimeters]" and that petitioner had a "resting gradient of 16 mmHg." Dr. Jiminez noted that "[n]o marked atrial enlargement was found[.]" Dr. Jiminez concluded that petitioner was at "low risk for [sudden cardiac death]." JE at 250-251.

Upon receipt of Dr. Jiminez's report, and the underlying raw data, Dr. Maron prepared a report for petitioner's counsel. Dr. Maron's report noted that petitioner "clearly has [HCM], probably

with mild ... outflow obstruction." He noted "a moderate degree of left ventricular wall thickening (i.e., 20 mm) ... confined to the anterior basal ventricular septum" and a "[l]eft atrial dimension ... enlarged at 51 mm." Dr. Maron's report stated that a "left atrial dimension [greater than] 50 mm suggests a distinct risk for atrial fibrillation in [HCM]." Dr. Maron's report concluded that petitioner's risk for sudden cardiac death "appears to fit the low-risk profile ... with the exception that his left atrial enlargement places him at risk for atrial fibrillation in the future." Dr. Maron's report also cautioned that "judgment about the risk can not be absolute and there remains a chance of sudden collapse or loss of consciousness." He concluded that he could not support a petition to reconsider a denial of petitioner's airman medical certificate. JE at 1-2.

Dr. Maron provided petitioner's counsel with several names of specialists who might be able to provide a second opinion. Petitioner's counsel subsequently contacted Dr. William J. McKenna, a professor of cardiac medicine at St. George's Hospital Medical School in the United Kingdom and, also, an expert on HCM, and whom Dr. Maron described as "on top" of his list of recommended specialists from whom to seek a second opinion. In March of 1998, Dr. McKenna performed additional tests upon petitioner, including an ECG, a 48-hour Holter monitor, and an echocardiogram. Dr. McKenna concluded in a report that the echocardiogram "revealed morphologically mild asymmetric septal

hypertrophy of 16 mm to 18 mm in the anterior septum at mitral valve and papillary muscle level" and noted that the "left atrial dimension was at the upper limit of normal for body surface area (4.7 cm)."[4] Dr. McKenna concluded that petitioner is "not at significantly greater risk of sudden death or an episode of impaired consciousness than a well matched normal male ex-smoker who does not have [HCM]."[5] JE at 77-79.

Petitioner reapplied for a first-class medical certificate on June 23, 1998, after forwarding Dr. McKenna's report and underlying test results to the FAA. The FAA-designated AME, Dr. Richard A. Kelly, withheld medical certification pending further evaluation, and, on July 21, 1998, in accordance with a recommendation from the FAA cardiology panel, the FAA requested petitioner to undergo a dobutamine stress echocardiogram. JE at 57.

Dr. Petro Nihoyannopoulos, also of the United Kingdom, and recommended by Dr. McKenna, performed the dobutamine stress echocardiogram on petitioner on August 20, 1998. Dr. Nihoyannopoulos found that petitioner had “[m]ild asymmetric septal hypertrophy with no resting gradient, increasing to a maximum of 196mmHG at maximal stress” and was “entirely

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[4] I.e., 47 mm.

[5] Dr. McKenna's report also stated that the "data set to address” the “risk of an episode of impaired consciousness that is not fatal” is “less well developed than that related to the identification of patients at risk of sudden death." JE at 79.

asymptomatic throughout with normal blood pressure response."[6] JE at 28. Dr. Nihoyannopoulos measured petitioner's left atrium as 49 mm, and measured petitioner's ventricular septum as 14 mm.

By letter of October 6, 1998, the FAA's Dr. Stephen Carpenter again denied petitioner's application for an unrestricted airman medical certificate. Dr. Carpenter's letter explained that petitioner's medical certificate application was denied pursuant to, again, FAR sections 67.113(b), 67.213(b) and 67.313(b) because of "a history of asymmetric septal hypertrophy and [IHSS]." JE at 15-16.

Petitioner filed a petition for review of the denial of medical certification on December 4, 1998. In response, Dr. Robert S. Poole, a cardiologist and manager of the FAA's Office of Medicine, requested that Dr. Maron, who had since become an FAA consultant, review petitioner's file. By letter dated December 15, 1998, Dr. Maron generally agreed with Dr. McKenna's conclusion that petitioner's risk for sudden cardiac death was low, but noted that "risk stratification profiles available for HCM ... address the risk for *death* and here we are interested equally in the risk for sudden impairment or incapacitation[,]" and that the risk data cited by Dr. McKenna were "largely meaningless." Dr. Maron also disagreed with Dr. McKenna's statement that petitioner's left atrium, measured by Dr. McKenna

[6] Dr. McKenna, who submitted the results of Dr. Nihoyannopoulos's tests, questioned the clinical significance of dobutamine-induced

to be 47 mm, was “at the upper limit of normal[,]” noting that “normal for an adult male is [less than or equal to] 38 mm.” Rather, Dr. Maron opined that:

> a left atrial dimension [greater than] 45 mm (and I believe it is 5 cm here) in a patient with HCM such as Captain Wade is indicative of a risk at sometime in the future for atrial fibrillation ... an arrhythmia experienced by fully 20% of all patients with HCM. The sudden onset of an unexpected paroxysm of atrial fibrillation could well lead to impaired consciousness and important incapacitation in the cockpit, particularly if this event occurred at a crucial moment.

JE at 6-7.

By letter of December 14, 1998, the FAA's Federal Air Surgeon, Jon L. Jordan, reaffirmed Dr. Carpenter's October 6 denial of petitioner's application for a first-class medical certificate, explaining that his denial was based on petitioner's “history of hypertrophic abstructive cardiomyopathy.” However, by letter of December 23, 1998, Federal Air Surgeon Jordan amended the denial letters of October 6 and December 14 by explaining that the denial of petitioner's medical application was based on petitioner's "history of [HCM]." JE at 3-5. Petitioner then initiated the present appeal.

Petitioner testified at the hearing, but the bulk of his case rested on the expert testimony of Dr. McKenna. The Administrator rested her case on the expert testimony of Dr.

(..continued)
gradients in an accompanying report. JE at 26-27.

Maron, as well as on the testimony of the FAA's Dr. Poole. Drs. McKenna, Maron and Poole all agreed that petitioner's condition placed him in the low-risk category for sudden death. The central issue at the hearing was petitioner's susceptibility to a non-fatal, incapacitating event while exercising his airman privileges.

In his initial decision, the law judge acknowledged the expertise of both Drs. McKenna and Maron, and noted that, as Dr. McKenna stated during his testimony, there was disagreement on the actual dimension of petitioner's left atrium. The law judge observed: "Depending on which measurement is used and which chart is used, [p]etitioner's risk of atrial fibrillation ranges from 22% with a 50 mm measurement with Dr. Maron's chart [citations omitted] to 47 mm measurement by Dr. McKenna and no significant risk of complications of atrial fibrillation." Initial Decision at 4. He then concluded that "[p]etitioner and his witnesses failed ... to prove or establish by a preponderance of the evidence that there was no risk for having an incapacitating event that would make him unable to safely perform the duties or exercise the privileges of [an] airman medical certificate." Id.

On appeal, petitioner raises numerous arguments, most of which go to issues other than the persuasiveness of the medical

testimony and have no merit.[7] However, we also read petitioner's brief to be an appeal of the law judge's ultimate decision that petitioner failed to demonstrate that he is medically qualified for the certificate he seeks.[8] The Administrator argues that the record supports the law judge's decision, and urges us to affirm it.[9]

In proceedings that challenge the denial of a medical certificate, the burden of proof is on petitioner to establish his medical qualifications by a preponderance of reliable, probative, and substantial evidence. Petition of Witter, NTSB Order No. EA-4500 at 3 (1996). In weighing medical testimony,

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[7] For example, petitioner argues that the law judge erred in requiring that he meet an impossible burden of proving that he was at "no risk" as a condition of obtaining his medical certificate, and that it was improper to allow HCM to be "absolutely disqualifying" in the absence of a validly-adopted regulation or standard to that effect. We read the law judge's decision, in context, to say that petitioner failed to prove he was not at an "unacceptable" risk.

[8] Petitioner also argues that the law judge erred in allowing Dr. Maron's testimony. This argument is based on the fact that Dr. Maron was initially hired by petitioner to assist with demonstrating he was medically qualified, and grounded in petitioner's conviction that Dr. Maron unscrupulously later became the Administrator's expert. We are not particularly troubled by this occurrence, and we note, in this regard, that our cursory review of the principles behind the physician-patient privilege indicates that no privilege would attach to the situation here.

[9] Petitioner also seeks oral argument in connection with this appeal. However, we have a well-developed record before us, and we do not believe our disposition of this case would be aided by the presentation of oral argument. The motion for oral argument is therefore denied. See 49 C.F.R. § 821.48(e).

the Board reviews expert testimony and draws conclusions based on the quality of the medical opinion. This quality depends on the logic, objectivity, persuasiveness, and depth of the medical opinion. Petition of Ruhmann, NTSB Order No. EA-3710 at 11 (1992).

Stated succinctly, Dr. McKenna is of the opinion that while petitioner has HCM, his risk of sudden death or incapacitation is "extremely low, and probably not dissimilar of" any male his age in the general population. Tr. I at 97. Dr. McKenna explained that HCM "usually develops during adolescence and it's usually completed in the sense that the thickening doesn't get worse after late adolescence [or] early adulthood." Tr. I at 71. According to Dr. McKenna, petitioner probably has had HCM since he was a teenager. Id. Dr. McKenna explained that the cell structure found in persons with HCM is myocyte, that is, "the muscle cells are completely disorganized in relation to each other" and that the condition is usually inherited. Tr. I at 69-70; 83. According to Dr. McKenna, most persons with HCM are never diagnosed with the condition. Tr. I at. 94.

Dr. McKenna testified that once a patient is diagnosed with HCM, a qualitative and quantitative assessment is undertaken to determine how the condition is impacting that patient's life quality (e.g., a symptomatic assessment), and whether the patient is at greater risk as a result of the condition (e.g., a risk assessment). Tr. I at 76. On the symptomatic side of the

evaluation, Dr. McKenna explained that the patient is queried about whether he or she has experienced physical limitations, or is capable of living a normal life, and then the patient's answers are confirmed with objective tests, such as, for example, metabolic gas exchange measurements to gauge the patient's physical performance to the measured performance expected of a person of similar age, gender and physical size. Tr. I at 76-77. On the risk assessment side, family medical history is evaluated, especially for instances of premature, sudden death, as well as the results of Holter monitor testing and the patient's blood pressure response to exercise testing. Tr. I at 77-78; 84.

Turning to the particulars of petitioner's condition, Dr. McKenna explained that his symptomatic assessment revealed that petitioner "has no symptoms and he leads a normal daily life, and he can work and exercise." He elaborated that petitioner is physically fit, exercises regularly, and his exercise test indicated that "his anaerobic threshold, which is a measure of efficiency, was [at] the level of a trained athlet[e]." Tr. I at 80. With regard to the risk assessment, Dr. McKenna explained that the most important indicator for someone of petitioner's age was the finding of a ventricular tachycardia, or arrhythmia, during a Holter monitor test. If the test is normal -- i.e., no abnormality, "which is associated with, in someone of [petitioner's] age, of about a threefold increased risk of sudden death," is found -- it is an accurate predictor that the patient

"is not at significant risk of a major complication" and no such abnormality was found in petitioner's test. Tr. I at 80-81. Of secondary importance in the risk assessment, according to Dr. McKenna, was petitioner's blood pressure reaction to an exercise test. In HCM patients at risk, systolic blood pressure which is expected to increase in response to exercise does not, indicating hemodynamic instability. Petitioner's blood pressure reaction was normal, however, indicating, according to Dr. McKenna, that petitioner can be "very reasonably assured" that he's "at low risk." Tr. I at 81-82. Finally, a review of petitioner's family medical history, which Dr. McKenna explained would point out HCM complications, indicated "reasonable to very good longevity" and "no premature sudden death." Tr. I at 83-84. "There's nothing that would alert you that this is a potentially high risk family that is passing on a gene that's particularly nasty and then a poor prognosis." Tr. I at 84.

Regarding the measurement of petitioner's left atrial dimension, Dr. McKenna stated persons have different-sized hearts, but there is an established range for what is considered normal by the medical community. The two primary "corrective factors" for this measurement, as applied by published tables used to derive a normal size measurement for a particular individual, are age and body surface area. Tr. I at 85. Using these charts, McKenna derived an upper-limit for normal left atrial dimension measurement for someone of petitioner’s age and

size as being "about 47 to 48 mm." Tr. I at 88. Dr. McKenna testified that he and several colleagues re-measured petitioner's left atrial dimension, and consistently found that it was between 47 and 49 mm. Dr. McKenna testified that left atrial dimension will increase with age, but that this measurement would be expected to remain at the upper limit of the normal range. Tr. I at 90.

Based on these observations, and upon being asked at the hearing about petitioner's "prognosis for some incapacitating event to come on suddenly," Dr. McKenna concluded:

> In the context of someone who doesn't have evidence of arrhythmia, either by symptoms, is not complaining of palpitation or by documentation on the tape recorder, Holter monitor; he hasn't fainted; he has mild morphology or hyperpathy; his hemodynamics as assessed by exercise testing is normal or from our experience he would be in the upper five to eight percent of our patient population in terms of what he can do; he's extremely fit and that's assessed and tested objectively[;] in that context, the slightly large atrium is not a risk and there's no data to indicate that it is a risk.
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> If you change the context and go away from someone who is effectively -- if you change the context and go back to the referral institution and say, does an enlarged left atrium associate to risk of atrial fibrillation; yes, it does. But those patients -- in isolation it doesn't, but in those patients you'll find other features. You'll find symptoms. You'll find arrhythmias on the tape recorder. You'll find the morphology is more severe.
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> So, in summary, our assessment is this mildly or borderline left atrial dimension does not represent a significant risk of

> either atrial fibrillation or of major complication from atrial fibrillation.[10]

Tr. I at 94-96.

Dr. Maron testified that HCM "involves many different facets" and "there are a number of features of the disease that not all patients have, so we speak of heterogeneity or diversity as really the number one characterization.... [U]npredictability I would have to say goes with heterogeneity as well." Tr. I at 229-230. Dr. Maron also testified that symptomatic or mildly symptomatic patients with HCM can die suddenly and unexpectedly,

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[10] When asked at the hearing about Dr. McKenna's pre-hearing report, Dr. Maron agreed with the assessment that petitioner was at low risk for sudden death, but took issue with Dr. McKenna's conclusion that petitioner is also not at risk for a non-fatal incapacitating event. "[I]f he means that nothing is going to happen because nothing has happened, then I would have to strongly depart because ... in terms of non-fatal incapacitation, [HCM] is unpredictable." Tr. I at 277. Dr. Maron generally faulted Dr. McKenna's report for combining his conclusions about petitioner's risk of sudden death with an equally-favorable prognosis of petitioner's risk of experiencing non-fatal incapacitating events, pointing out that clinical or empirical evidence is lacking for adequately predicting risk of non-fatal incapacitating events. Tr. I at 276-284. When asked about Dr. McKenna's inference in his report that it is possible to identify a low risk cohort for impaired consciousness, Dr. Maron testified:

> I think that we are certainly a whole lot closer to identifying low-risk patients for sudden death in this disease. And I would agree with Bill McKenna on that. But where is the evidence for the same thing to be said of impaired consciousness? I don't know where those data are, and I think we heard that it is virtually non-existent.

Tr. I at 284.

and that sudden cardiac death may be the first symptom of the disease. Tr. I at 232-233; Exhibit ("Ex.") A-6.

Dr. Maron testified that "atrial fibrillation is part of" HCM, and that, of the minority of HCM patients who encounter this condition, an enlarged left atrium "is our marker for being predisposed to develop atrial fibrillation." Tr. I at 238. "It's a very tight marker and one that's been used clinically for a long time." Id. Dr. Maron characterized atrial fibrillation as "very important ... I can think of no worse clinical situation probably than having atrial fibrillation in [HCM], at least for many patients[.]" Id. According to Dr. Maron, "[a]trial fibrillation is a particularly important arrhythmia in [HCM] because it develops in the substantial proportion of adult patients.... Sudden onset of atrial fibrillation often causes rapid clinical deterioration by reducing diastolic filling ... and also reduces cardiac output usually as a consequence of high ventricular rate." Tr. I at 241. HCM patients experiencing atrial fibrillation, according to Dr. Maron, could experience the following symptoms or conditions: "shortness of breath, chest pain, dizziness, near fainting, fainting, cardiovascular decompensation[.]" Tr. I at 239. It is also possible, according to Dr. Maron, for HCM patients experiencing atrial fibrillation "to develop heart failure, even develop clots in the atria even rather rapidly and have emboli." Id. Although some patients "can go into atrial fibrillation and not realize it," according

to Dr. Maron, he estimated that "the vast majority of patients, let's say eight to nine out of ten, who go into atrial fibrillation acutely do have symptoms, are cognizant they are in the arrhythmia, and usually have some distracting and uncomfortable and important symptomology." Tr. I at 243.

Turning to petitioner's condition, in particular, Dr. Maron concluded that petitioner's "risk for a sudden ... incapacitation or disability is high. Unacceptably high." Tr. I at 251. Regarding petitioner's left atrium measurements, Dr. Maron discussed the various measurements and concluded that, despite variations from measurement to measurement, "these are all in the same ballpark, so to speak. They place the left atrial dimension about 50 millimeters, give or take, that's what we're talking about." Tr. I at 254-261. Dr. Maron also testified that Dr. McKenna's application of the left atrium size chart was problematic, in that "there's clearly not agreement among cardiologists about how to apply it" and that the convention among the cardiological community is to "regard an upper limit of 40 [mm] for the left atrium" measurement. Tr. I at 287.[11] "And

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[11] Dr. Maron also testified that Dr. McKenna incorrectly derived from the body surface area chart a normal upper limit measurement of 47 for someone of petitioner's size and age.

> What I think was done earlier was to plot between the 40 and 60 [age] line. You can't do that. Those data are not continuous between the two lines. Within the 40 line happens to be patients from [age] 40 to 59. That's how those data were assembled. It was

I do take strong disagreement with the idea that we should regard, for a man of average size, 47 [mm] as the upper limit of normal. That just doesn't correspond to daily clinical cardiologic practice whatsoever in my mind and experience." Tr. I at 290. Dr. Maron testified that, in his opinion, petitioner has a larger than normal left atrium, and, in terms of risk of developing atrial fibrillation, it is clinically significant. Tr. I at 291-296; Ex. A-10.

Dr. Maron also testified that, based on his review of a "non-selected"[12] population of 297 HCM patients in the upper

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(..continued)

> not a continuous spread. So to mark or extrapolate between the age lines like that doesn't correspond to the actual raw data. So what you have to do, and I've done this many times, is use one line or the other that comes closest to the individual's age. Tr. I at 289-290.

Applying the chart, correctly, according to Dr. Maron, would yield an upper limit for normal left atrial size measurement of 45 mm (and not, as Dr. McKenna testified, of 47 mm) for a man of petitioner's age and size. Dr. Maron also stated, however, that "I've always had trouble with this graph ... about whether it was truly relevant for left atrial dimension." Tr. I at 290.

[12] The term refers to a conscious effort to avoid “referral bias” or skewed results that might occur if the data set were obtained from "tertiary referral," for example, facilities specializing in HCM where patient's HCM-related conditions are likely to be more acute or pronounced than what would be found, on average, amongst the population at large. "These are patients that are not very selected, in the sense that they are residents of the five upper Midwest area, they haven't been referred in, nor have they been referred out. They are largely regional. Not subject to a lot of the bias that could be in a population. So this, we feel this is closer to the real disease, if you like, for lack of a better term. Without selection bias." Tr. I at 262; 312.

Midwestern states, 18-20 percent had experienced fainting or severe dizziness, and 17 percent had experienced atrial fibrillation. Tr. I at 262-264; Ex. A-8.[13] Moreover, according to Dr. Maron, applying the analysis to all 297 patients over a mean time period of eight years, 46 percent had experienced an incapacitating event (at an average on-set age of 45 years). Id.[14] Petitioner argues that Dr. Maron's study is flawed, *see* Petitioner's Brief at 6-7, and is not predictive of petitioner's condition because none of the underlying patients in Dr. Maron's study have the medical history and symptoms exhibited by petitioner. *See also* Tr. 92-94 (Dr. Maron discussing referral bias and his opinion that most "asymptomatic" HCM patients such as petitioner are generally never identified out of the general population).

Dr. Poole testified that the FAA denied petitioner's application for an unrestricted first-class medical certificate because of "his history of [HCM] and its resultant risk for

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[13] Dr. Maron also referred during his testimony to a similar "cohort study describing the disease in another ... regional population in the Tuscany area, Central Italy." Tr. I at 265; Ex. A-7. In that study, which Dr. Maron agreed with as similar to his own findings on the upper Midwest HCM patients, "[a]trial fibrillation proved to be ... relatively common, the percentage here is 28 percent[.]" Tr. I at 267; Ex. A-7.

[14] For purposes of Dr. Maron's study of the 297 patients, "incapacitating events" were individually tallied as either fainting, near fainting, severe dizziness, the onset of acute atrial fibrillation, HCM-related sudden death from cardiac arrest, or non-fatal HCM-related cardiac arrest. Tr. I at 262.

incapacition." Tr. II at 19. In particular, according to Dr. Poole, the FAA was concerned about petitioner's risk of "syncope, near-syncope, dizziness, chest pain, shortness of breath, [or] palpitations." Tr. II at 20. Dr. Poole also explained that petitioner "has a large left atrium which would put him at risk for atrial fibrillation." Id. According to Dr. Poole, "even the subtle incapacitation that may occur with mild distraction due to palpitation could ... have serious implications." Tr. II at 21. Dr. Poole, however, ultimately deferred to the judgment of Dr. Maron when asked about the FAA's quantification of petitioner's "risk of incapacitation in the aviation environment as a result of his [HCM]." Id.

At its essence, this case presents us with two competing premises, the Administrator's expert's apparent belief that an airman with petitioner's morphology poses an unacceptable risk unless it can be shown otherwise, and petitioner's expert's apparent opposite tenet. We find, however, Dr. McKenna's testimony as a whole to be more persuasive, in large part because his analysis is more focused on the petitioner's actual morphology and symptoms. Therefore, although we do not doubt the statistics cited by Dr. Maron's studies, we believe Dr. McKenna's analysis of petitioner's condition to be the more cogent and persuasive assessment of the risks they might pose to petitioner

for sudden incapacitation.[15] We therefore conclude, after comparing petitioner's evidence to that presented by the Administrator, that petitioner has carried his burden of demonstrating that he is medically qualified to hold an unrestricted first-class medical certificate.

ACCORDINGLY, IT IS ORDERED THAT:

1. Petitioner's appeal is granted[16]; and

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[15] *See, e.g.*, JE at 78-79 ("What is his risk of major complication which could produce impaired consciousness? The major complications of hypertrophic cardiomyopathy are arrhythmia, emboli and sudden death. The annual mortality from sudden death in major cardiac centres is 1% to 2%. The pressure response during exercise identify the high risk cohort with a high level of sensitivity but low positive predictive accuracy because the majority of patients with any one of the aforementioned risk factors do not go on to die suddenly. The absence of risk factors however is of high (97%) predictive accuracy for survival and in a model which we have recently developed, an individual with Mr. Wade's clinical profile would have 100% survival in six years. What is the risk of an episode of impaired consciousness that is not fatal? The data set to address this issue is less well developed than that related to the identification of patients at risk of sudden death. The mechanisms of syncope include mycocardial ischaemia, supraventricular arrhythmia, particularly paroxysmal atrial fibrillation and abnormal vascular responses, [and] inappropriate vaso-dilation[]. Individually these may trigger an episode, or, interact collectively, to cause an episode. Mr. Wade has never experienced symptoms suggestive of ischaemia or arrhythmia. Holter monitoring and stress thallium scintigraphy have revealed no relevant abnormalities and vascular responses assessed during bicycle exercise were entirely normal.... All the evidence suggests that Mr. Wade has a benign variety of hypertrophic cardiomyopathy and that he is at very low risk of disease related complications including episodes of impaired consciousness.").

[16] The Administrator has moved to strike two rule 48(e) filings by petitioner. The first filing cites a federal district court decision concerning the admission of expert testimony, and the second one cites a recent Supreme Court case involving deference to agency decisions. The motions are granted. As noted by the

2. The Administrator's order denying respondent's application for an unrestricted first-class medical certificate is reversed.

HAMMERSCHMIDT, GOGLIA, and BLACK, Members of the Board, concurred in the above opinion and order. BLAKEY, Chairman, did not participate. CARMODY, Vice Chairman, did not concur, and submitted the following dissenting statement:

An airman seeking reversal of a denial by the Administrator of a medical certificate must demonstrate, by a preponderance of the evidence, that he or she is medically qualified. In this case that means that the petitioner, an airline pilot, was obligated to show that, contrary to the judgment of the Federal Air Surgeon, the hypertrophic cardiomyopathy from which he suffers does not present an unacceptable risk of sudden incapacitation while at the controls of an aircraft. As I read the record, the petitioner did no more than establish that there is disagreement among top cardiologists over the magnitude of the risk posed by individuals within the general population who have a heart condition such as his. I did not find the opinion of his experts, who did not believe that his condition was a source of grave concern, so compelling that it should be preferred over the equally cogent contrary opinion of the Administrator's medical experts. Consequently, I would affirm the law judge's assessment that the petitioner had not proved that he was medically qualified for an unrestricted first-class medical certificate.

(..continued)
Administrator, the first filing identifies a case that was published months before the appeal brief was filed, and therefore could have been cited and discussed in that document, and the second filing contains argumentation relating to the case it cites that is prohibited by the rule. Rule 48(e) may not be used to "correct omissions in briefing," and a party must seek advance Board permission before filing what amounts to a supplemental brief.